UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,151	04/15/2002	Bernard Klein	02021	6370

23338 7590 02/10/2006

DENNISON, SCHULTZ, DOUGHERTY & MACDONALD
1727 KING STREET
SUITE 105
ALEXANDRIA, VA 22314

EXAMINER	
EWOLDT, GERALD R	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,151	KLEIN ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2005 and 01 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-16,18-20 and 22-24* is/are pending in the application.

4a) Of the above claim(s) *23 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-16, 18-20, and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 23 and 24 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 1-13, 17, and 21 have been canceled.

Claims 14-16, 18-20 and 22 are being acted upon.

2. Applicant's amendment, filed 12/01/05, and remarks, filed 10/25/05, are acknowledged.

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

A) The citizenship of Inventor Tarte has not been identified.

Applicant indicates that a substitute declaration is being prepared.

4. Applicant's reasons for the changes to the instant specification are acknowledged. The amendments have been entered.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 14-16, 18-20 and 22 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically:

As set forth previously, In Claim 14, the term "mobilization" is vague and indefinite. While the specification discloses that mobilization may be effected by chemotherapy (page 5), this disclosure does not comprise an actual definition of the term, and Claim 19 indicates that other "mobilization" techniques are encompassed by the limitation.

Applicant's arguments, filed 10/25/05, have been fully considered but they are not persuasive. Applicant argues that

mobilization refers to "the release of cells into the circulatory system following physical, environmental, or other, factors impacting on the immune system".

Applicant is advised that this definition is not found in the specification. The provision of evidence that this definition is routinely accepted in the art might obviate the rejection.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 14-16, 19, 20, and 22 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

As set forth previously, There is insufficient written description to show that Applicant was in possession of a "an interleukin that blocks differentiation towards the macrophage pathway" as recited in Claim 14. While the specification discloses that said interleukins include IL-4 and IL-13, the specification provides no further guidance. Thus, the skilled artisan is left with only a functional description for the identification of the interleukin of the claims. Said functional description alone, absent any hint of the structural features linking the interleukins, comprises an inadequate written description. Likewise the "cell growth factor" of Claim 19 is inadequately described. In this instance no additional description is disclosed for this potentially unlimited genus of factors. Thus, again, no common structural feature has been identified and the written description is considered to be inadequate.

Applicant's arguments, filed 10/25/05, have been fully considered but they are not persuasive. Applicant argues that the specification is enabling for the terms.

Applicant is advised that no rejection for lack of enablement has been made. The rejection is for lack of adequate written description for the genus of "interleukins that block differentiation towards the macrophage pathway" of Claim 14 (and now, additionally, Claims 16 and 20) and the genus of "cell growth factors" of Claim 19.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 14-16, 19, 20, and 22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Tarte et al. (1998, IDS) in view of U.S. Patent No. 5,405,772.

As set forth previously, Tarte et al. teaches a method of obtaining dendritic cells (DCs) comprising cultivation of mobilized mononuclear cells (obtained from a multiple myeloma patient who would have had some chemotherapy) in serum-free medium, GM-CSF and IL-4 or IL-13, for 5 days followed by 2 days in TNFα culture (see particularly page 1853, columns 2, *Results*).

The reference teaching differs from the claimed invention only in that it does not teach the cultivation of said cells in human albumin.

The '772 patent teaches that serum albumin, particularly human albumin, is a routine component of serum-free cell culture medium (see particularly column 10, line 66-column 11, line 8), particularly, hematopoietic cell culture medium (see particularly column 8, lines 17-20).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform the method of obtaining DC of Tarte et al., including human albumin in the cell culture, as taught by the '772 patent. One of ordinary skill in the art at the time of the invention would have been motivated to include human albumin because it was a routine component of hematopoietic cell culture medium, as taught by the '772 patent. Note that the limitations of Claims 20-22 comprise only the routine optimization of the amount of cytokines and albumin used in the culture method and would have fallen well within the purview of the skilled artisan at the time of the invention. Said additional limitations do not render the claimed method patentably distinct.

Applicant's arguments, filed 10/25/05, have been fully considered but they are not persuasive. Applicant argues that the cells obtained through the method of the instant claims, i.e., a method comprising adding human albumin to the medium of the Tarte et al. reference, results in a considerable increase in cell viability. Applicant submits Tables A and B in support.

Applicant appears to be arguing that the method of the instant claims achieves unexpected results. Applicant is advised that an assertion of unexpected results comprises a secondary issue. In making such an assertion Applicant is admitting that the invention is obvious, however, patentability

lies in the unexpected result. Additionally, Applicant is advised that the unexpected results must be disclosed in the specification and not first asserted in post-filing arguments. Regarding the data of Tables A and B, absent a proper declaration detailing the experiments from which the data was obtained, and who obtained said data, said data cannot be properly considered. Absent a persuasive showing of unexpected results the rejection stands for the reason of record.

11. Claim 18 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Tarte et al. (1998, IDS) in view of U.S. Patent No. 5,405,772, as applied to Claims 14-16, 19, 20, and 22 above, and in further view of Kalinski et al. (1998, IDS).

As set forth previously, Tarte et al. and the '772 patent have been discussed, above. The teachings of the combined references differ from the claimed invention only in that they do not teach the additional use of prostaglandin E2 (PGE2) in the cell culture.

Kalinski et al. teaches that PGE2 synergizes with TNFα in DC cell culture in inducing DC maturation (see particularly page 2805, column 2, *Results*).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform the method of obtaining DC of Tarte et al., including human albumin in the cell culture, as taught by the '772 patent, as well as PGE2, as taught by Kalinski et al. One of ordinary skill in the art at the time of the invention would have been motivated to include PGE2 in the method given the teachings of
Kalinski et al. that PGE2 synergizes with TNFα in DC cell culture in inducing DC maturation, thus, providing an improved method for obtaining DC from culture.

Applicant's arguments, filed 10/25/05, have been fully considered but they are not persuasive. Applicant argues that there is no indication that the PGE2 of Kalinski et al. would have the same action in the serum-free medium of the method of the instant claims as it did in the medium with fetal calf serum used in the reference.

There is no teaching in the instant specification or of record that PGE2 interacts with fetal calf serum and that fetal calf serum is required for the synergy between PGE2 and TNFα as taught by Kalinski et al.

12. No claim is allowed.

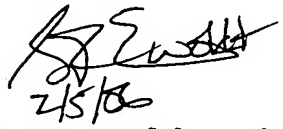
13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action

is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

Please Note: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



2/5/06

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600